K103274 p1/2

sentinelle MEDICAL

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AUG 18 2011

510(k) Summary

Submitter: Sentinelle Medical Inc.

Address: 555 Richmond Street West, Suite 800
Toronto, Ontario, M5V 3B1
Canada

Contact: Cameron Piron

Telephone: 647-258-3601

Date: August 17th, 2011

Trade Names: Sentinelle Endo Coil Array for Pelvic Imaging

Common Names: Sentinelle Pelvic Solution, eArray, Prostate Coil Array, Female Pelvic Coil Array

Classification Name: Accessory to Magnetic Resonance Diagnostic Device,
Class II as described in 21 CFR 892.1000

Product Code: MOS

Predicate Devices: K053042 – MEDRAD 1.5T Pelvic Imaging System Interface Device

Device Description:
The Endo Coil Array is a reusable, rigid transrectal or transvaginal receive-only MRI coil array similar to other products. The Coil Array housing has a cylindrical shape similar to transrectal and transvaginal ultrasound probes.

The Coil Array is held by an articulating Stabilization Arm that is attached to a Patient Support. The Patient Support is available in both Transporter and Tabletop versions, which dock to the scanner or are placed on top of the scanner's existing couch respectively.

Intended Use:
The Endo Coil Array is a receive-only MRI coil array for imaging (including spectroscopy) in the prostate, cervix and colon and surrounding pelvic tissues in adult populations with clinically present anus and rectum or vagina. The Endo Coil Array can be used with many commercial MRI scanners. This device is for exclusive use by a qualified medical professional under the order of a physician. For use with GE, Toshiba and Siemens 1.5T MR systems.

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Indications for Use:
The Sentinelle Endo Coil Array is a receive-only MRI coil array which must be used by a qualified medical professional to obtain images of (including spectroscopy images) the prostate, cervix and colon and the surrounding tissues in the pelvis. The Coil Array is a reusable transrectal or transvaginal device that can be high level disinfected. This product is for exclusive use on adult populations with clinically present anus and rectum or vagina. For use with GE, Toshiba and Siemens 1.5T MR systems.

Substantial Equivalence Summary:

Proposed Device	Predicate Device	Substantially Equivalent Aspect
Endo Coil Array	MEDRAD Interface Device	• Transrectal receive-only MRI coils for imaging. • Regions of interest: Prostate, Colon, Cervix and surrounding tissue. • For use exclusively by trained medical professionals.

Performance Testing:
Non-clinical performance testing was done to ensure the device performed equivalently to predicates in the areas of SNR comparison, spectroscopy, and image uniformity per NEMA 9:2008 with no additional concerns of safety or effectiveness.

Comparison to Predicate:
In the opinion of Sentinelle, the intended use and technological characteristics of the Sentinelle Endo Coil Array are substantially equivalent to those of the predicate devices and do not pose any issues for its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Sentinelle Medical, Inc.
c/o Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

AUG 18 2011

Re: K103274
Trade Name: Sentinelle Endo Coil Array for Pelvic Imaging
Regulation Number: 21 CFR. 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 25, 2011
Received: July 26, 2011

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K103274

Device Name: Sentinelle Endo Coil Array for Pelvic Imaging

Indications for Use:

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Prescription Use ___✓____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103274